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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 417

[Docket No. FSIS-2012-0007]

HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations and request for comments

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this notice to inform establishments producing not-ready-to-eat (NRTE) ground or otherwise comminuted chicken and turkey products that they must reassess their Hazard Analysis and Critical Control Points (HACCP) plans for these products to take into account several recent Salmonella outbreaks associated with consumption of comminuted NRTE turkey products. No sooner than 90 days following publication of this notice, Agency inspection program personnel (IPP) will begin verifying that establishments that manufacture comminuted NRTE turkey or chicken product, as a final or intermediary product for further processing as NRTE product, have reassessed their HACCP plans for these products.

This notice also describes how FSIS will determine whether the association of NRTE meat or poultry product with an

outbreak would make subsequently-produced like product adulterated.

In addition, FSIS is expanding its Salmonella Verification Sampling Program for Raw Meat and Poultry product to include all forms of non-breaded, non-battered comminuted NRTE poultry product that are not destined under company control programs for further processing into RTE products in official establishments.

Finally, this notice announces that FSIS will apply its Category 1 performance measure based on current performance standards for ground chicken and turkey product to comminuted poultry to mark the level of process control that all establishments producing such products should maintain. No sooner than 90 days after publication of this notice, the Agency will begin sampling to determine the prevalence of Salmonella in comminuted poultry and will use the results from this sampling to develop performance standards for these products. For reasons discussed later, FSIS has not tested NRTE comminuted poultry products, other than ground chicken and ground turkey, for Salmonella. In addition, FSIS is likely to develop Campylobacter standards for these products following validation of an analytic method.

FSIS invites comments on this notice.

DATES: The Agency must receive comments by [INSERT 90 DAYS FROM DATE OF PUBLICATION IN FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue, SW, Mailstop 3782 Room 8-163A, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E Street, SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2012-0007. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street, SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: For information: Contact Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, at (202) 205-0495, or by fax at (202) 720-2025.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 453 et seq.) to protect the health and welfare of consumers by preventing the distribution in commerce of meat or poultry products that are adulterated or misbranded. In pursuit of its goal of reducing the risk of foodborne illness from meat and poultry products to the maximum extent possible, FSIS issued final regulations on July 25, 1996, that mandated the development and implementation of Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) Systems by federally inspected establishments (61 FR 38806). These regulations require that federally inspected establishments take preventive and

corrective measures at each stage of the food production process where food safety hazards are likely to occur. The HACCP regulations (9 CFR 417.2(a)) require establishments to conduct a hazard analysis to determine what food safety hazards are reasonably likely to occur in the production process of particular products and to identify the preventive measures that the establishment can apply to control those hazards.

Section 417.2(a)(1) of the HACCP regulations states that a food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish control measures because the hazard historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. Whenever a hazard analysis reveals that one or more hazards are reasonably likely to occur in the production process, the regulations require that the establishment develop and implement a written HACCP plan that includes specific control measures for each hazard identified (9 CFR 417.2(b)(1) and (c)).

Section 417.4(a)(3) of the regulations requires that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Because the recent outbreaks discussed in this notice were associated with many

individual consumers in multiple States, the occurrence of these outbreaks could represent a change in the sanitary conditions involved in the manufacture of these products and is a change that could affect the hazard analysis or alter the HACCP plans for comminuted poultry products. Although the recalls described in this notice have involved NRTE comminuted turkey products, NRTE comminuted chicken products are produced in a similar manner. Therefore, FSIS is requiring that establishments reassess HACCP plans for comminuted NRTE chicken or turkey products, including final products or intermediary product for further processing as NRTE product. Such product includes any NRTE chicken or turkey product that has been ground, mechanically separated, or hand- or mechanically deboned and further chopped, flaked, minced or otherwise processed to reduce particle size.

## II. Findings Associated with Recent Outbreaks

In February 2011, the Wisconsin Department of Health and Family Services (WDHFS) notified FSIS of a case-patient hospitalized with a confirmed Salmonella Hadar infection who had consumed turkey burgers within the incubation period of illness onset. Leftover product tested positive for the pathogen associated with the outbreak. The clinical and product isolates also exhibited similar antimicrobial resistance. In March 2011, Colorado notified FSIS of a case-patient with

multiple drug resistant Salmonella Hadar who had consumed the same brand of turkey burgers before becoming ill. Turkey burger from the case-patient's home was positive for the pathogen associated with the outbreak. Shopper card information was used to determine that the case-patient's family had purchased the same brand of turkey burgers in January 2011. Later that month, the Ohio Department of Health notified FSIS of a case-patient hospitalized with Salmonella Hadar with a history of consuming the same brand of turkey burgers. The three case-patients with detailed food histories reporting these turkey burger exposures were all hospitalized overnight. In mid-January 2011, the Minnesota Department of Agriculture's retail food sampling program had detected the pathogen associated with the outbreak in the same brand of NRTE turkey meatloaf with gravy product with nationwide distribution. In March 2011, the New Mexico Department of Health had detected the outbreak strain of Salmonella Hadar in a ground turkey product from the same company during routine National Antimicrobial Resistance Monitoring System (NARMS) retail meat study testing (no illnesses resulted from consumption of these turkey products). The producing establishment voluntarily recalled approximately 54,960 pounds of ground turkey product. Information on this recall can be found on the FSIS web page

(<http://www.fsis.usda.gov>), through the ``FSIS Recalls`` link, under recall case number 028-2011.

In response to the events, the Agency conducted a Food Safety Assessment (FSA) at the establishment in April-May 2011. An FSA is performed to assess the design and validity of food safety systems in an establishment. FSAs are conducted routinely and periodically and also "for cause" when prompted by a positive sample result, production and shipment of adulterated product, or any other high priority food safety related incident. FSIS issued a Notice of Intended Enforcement Action (NOIE) to this establishment in early May due to lack of validated cooking instructions, among other findings. Specifically, the cooking instructions prescribed a certain number of minutes for cooking per patty side, but the establishment's validation cooking study did not demonstrate that the cook time and cooking methods prescribed in these instructions ensured that a safe internal temperature is reached. In response to the NOIE, the establishment decreased its patty thickness, revalidated cooking instructions, and changed its consumer package instructions to recommend cooking to 165 degrees Fahrenheit. The establishment also implemented antimicrobial treatments in product manufacture and made other changes in response to the NOIE. FSIS verified that the establishment was implementing effective Salmonella controls.



The establishment associated with this outbreak is not a slaughter establishment and receives raw product for grinding and ground product for blending from other establishments in its corporate structure. The recalled product was produced at this establishment by blending turkey ground at slaughter establishments within its corporate structure.

Through review of records, FSIS found that at the time of the outbreak, this further processing establishment had not, as cited above, provided validated cooking instructions for the recalled product, did not use interventions other than temperature control on raw parts for grinding, and did not prevent lots from contaminating each other by cleaning and sanitizing blending and grinding equipment between lots. FSIS also found that in the months leading up to the outbreak, the establishment that manufactured the product associated with the outbreak may not have had adequate controls to prevent or reduce Salmonella.

In May 2011, FSIS became aware of a cluster of 29 Salmonella Heidelberg illnesses from 18 states. Additionally, three ground turkey samples collected as part of the NARMS retail testing program (two in New Mexico and one in Minnesota) were included in the cluster; the MN sample was resistant to ampicillin, streptomycin, tetracycline, and gentamycin. Interviewed case-patients who had consumed turkey mentioned

several brands, including a number of store brands. FSIS issued a public health alert based upon the investigative findings on July 29, 2011, by which time there were 77 case patients from 26 states. As part of the outbreak investigation, the California Department of Public Health collected ground turkey samples from retail stores and tested them for Salmonella. On August 3, 2011, the producing establishment voluntarily recalled approximately 36 million pounds of ground turkey. Information on this recall can be found on the FSIS web page (<http://www.fsis.usda.gov>), through the ``FSIS Recalls`` link, under recall case number 060-2011. FSIS requested that the establishment recall product based on outbreak investigation data implicating the establishment as a supplier of product linked to human illness. FSIS suspended inspection for the NRTE grinding operations producing the implicated products at the establishment.

The establishment responded with modifications to its food safety system to improve its interventions designed to control Salmonella. The establishment's stated goal had been to meet the FSIS Salmonella performance standard for ground turkey (49.9 percent positive or less) (9 CFR 381.94(b)(1)). The establishment was depending solely on non-specific Salmonella controls to prevent further illness from its product. FSIS

allowed the establishment to resume operations to validate those modifications.

FSIS initiated an FSA and scheduled an Incident Investigation Team (IIT) review at the establishment. An IIT review is convened to investigate and provide information regarding a non-routine incident involving the adulteration of FSIS-regulated product or a significant event or potential public health issue. This IIT was convened in response to the outbreak linked to poultry product and repetitive food safety concerns identified in the review of establishment microbiological sampling and testing results by the FSIS District Office directing the investigation. The IIT investigation at the establishment showed that the establishment's umbrella corporation was unable to substantiate that it had controlled the pathogen associated with the outbreak in its source products. Testing of the establishment environment and poultry product by FSIS found additional evidence of the pathogen associated with the outbreak. Further, while the establishment was on track to meet the performance standard of 49.9 percent positive for generic Salmonella and validate its interventions, it had not correlated the standard to the effective control of the pathogen associated with the outbreak. The establishment was unable to substantiate that the

non-specific Salmonella controls it had initiated were sufficient to prevent further illness from comminuted product.

Establishment data indicated, furthermore, that the use of mechanically deboned and separated product increased the likelihood of Salmonella contamination. As noted below, both mechanically deboned product and mechanically separated product were used in the product associated with one of the outbreaks discussed in this notice. This appears to have been due to the establishment using antimicrobial treatments on some but not all source materials and specifically not on mechanically separated source materials.

Based on information from the FSA and IIT, FSIS issued an NOIE on the same NRTE ground processes previously suspended to provide the establishment the opportunity to demonstrate compliance as directed by 9 CFR 500.4(a). This resulted in a new suspension of inspection for the specified NRTE ground processes until the establishment was able to demonstrate effective controls. On September 11, the producing establishment voluntarily recalled 185,000 pounds of ground turkey. Information on this recall can be found on the FSIS web page (<http://www.fsis.usda.gov>), through the ``FSIS Recalls`` link, under recall case number 071-2011.

### III. Reassessment in Response to Outbreaks

Because the recent outbreaks discussed above have been directly associated with illness in many unrelated individuals in multiple states, these outbreaks, in the Agency's view, represent evidence of a material change in the effectiveness of what heretofore had been regarded as necessary and appropriate sanitary conditions required to manufacture safe and wholesome product. As such, the occurrence of these outbreaks is a change that could affect the hazard analysis or alter the HACCP plans for such products and like products. Therefore, establishments that produce NRTE comminuted turkey or chicken poultry products (including ground, mechanically separated, or hand- or mechanically-deboned poultry that is further chopped, flaked, minced, or otherwise processed to reduce particle size but not battered or breaded) in final form or as an intermediary product must evaluate the information discussed above to determine whether their HACCP plans for these products adequately address biological hazards, particularly Salmonella. An establishment that produces comminuted poultry and has already taken these outbreaks into account in a HACCP plan reassessment for these products is not required to do so again, provided the establishment has documented its reassessment in its hazard analysis or HACCP plans, or a record or reassessment, and makes this evidence available to FSIS inspection program personnel.

The investigations conducted at establishments associated with the outbreaks showed that sanitation procedures are particularly important in the production of ground and comminuted poultry products. When conducting a reassessment that takes these outbreaks into account to determine whether HACCP plans for NRTE comminuted poultry products adequately address biological hazards, Salmonella in particular, establishments should evaluate the adequacy of their sanitation procedures for processing equipment, including grinders, blenders, pipes, and other components and surfaces in contact with the product. Thus, Sanitation SOPs, other prerequisite programs, or HACCP plans should address procedures that ensure that all slaughter and further processing equipment, employee hands, tools, and clothing, and food contact surfaces are maintained in a sanitary manner to minimize the potential for cross contamination within and among lots of production. In addition, FSIS expects establishments to ensure that slaughter and dressing procedures are designed to prevent contamination to the maximum extent possible. Such procedures should, at a minimum, be designed to limit the exterior contamination of birds before exsanguination, as well as minimize digestive tract content spillage during dressing process.

Establishments producing NRTE comminuted poultry products should ensure that cooking instructions are validated,

especially if the instructions explain how to cook the product to attain an end-point temperature of 165 degrees Fahrenheit (e.g., when grilling patties, cook from the unfrozen state on each side for "X" minutes for a patty of "Y" thickness; bake uncovered in an oven at "Z" degrees for "A" minutes).

Establishments producing NRTE comminuted poultry products should also consider lotting practices (distinguishing one portion of production from another such that they are microbiologically independent) and ability to prevent lots from contaminating each other, including not carrying over production; cleaning and sanitizing between lots; and being able to trace back product to originating slaughter establishments (if applicable), grow-out houses, hatcheries, and breeding flocks. Such process control procedures may be instrumental in reducing the impact of potential future product recalls.

Establishments producing NRTE comminuted poultry products should evaluate the adequacy of any Salmonella interventions applied to product source materials or to product during or after grinding or blending. These establishments should also evaluate these interventions for their ability to reduce Salmonella (expressed as "log reduction"). When they are evaluating the effectiveness of these interventions, establishments should consider incoming variability of

Salmonella levels in live birds (at establishments that slaughter) and on parts (at establishments that use parts in comminuted product manufacturing).

If they have not already done so, establishments producing NRTE ground and comminuted poultry products should consider implementing purchase specifications that require raw materials used to produce such products to have been treated with an intervention shown to reduce Salmonella. If establishments producing NRTE comminuted poultry products require their suppliers (both within and outside their corporate structure) to meet such specifications, they should also ensure that their suppliers actually meet these purchase specifications. Establishments could incorporate such specifications in their HACCP plans, in their Sanitation SOPs, or in other prerequisite programs.

Establishments producing comminuted poultry should also consider serotype information, focusing on presence and trends in the serotypes of human health concern identified by the Centers for Disease Control and Prevention (CDC) in the CDC top 30 serotypes list (available at <http://www.cdc.gov/ncezid/dfwed/PDFs/SalmonellaAnnualSummaryTables2009.pdf>). FSIS provides guidance, including data on serotype information to establishments that have had Salmonella HACCP verification testing performed by FSIS. This guidance



explains that serotype information can be used to better focus food safety efforts to protect public health. For example, compiled serotype information can assist an establishment's efforts to identify interventions it may use and in that way help address the problem.

Finally, establishments producing NRTE comminuted poultry products should consider pre-harvest factors and interventions that may influence Salmonella contamination in NRTE comminuted poultry products (including breeder flock Salmonella status, hatchery management, biosecurity and pest control, feed manufacturing and feed withdrawal practices, and sanitation of pre-harvest environments including transport crates).

Although comminuted livestock products (e.g., beef and pork) are similarly produced, this notice is specific to poultry. Historically, ground chicken products have the highest Salmonella spp. percent positive rates of all FSIS-regulated product classes. Further, three of the five most common Salmonella serotypes known to cause human illness are consistently found more in ground chicken. As such, available data suggests a continued focus on poultry products will reduce salmonellosis. Prudent manufacturers of comminuted meat products, however, should be aware of the factors contributing to the recent ground turkey product outbreaks and consider the

information in this notice with regard to assessing whether their food safety systems present similar vulnerabilities.

#### IV. FSIS Actions to Enforce and Facilitate Compliance with the Reassessment Requirement

FSIS will instruct inspection program personnel to ensure that all establishments producing non-breaded, non-battered NRTE comminuted chicken or turkey, including small and very small establishments that may not belong to a trade association, are aware that the Agency has issued this notice.

No sooner than 90 days following publication of this notice in the Federal Register, FSIS will instruct inspection program personnel to begin conducting a checklist survey in chicken and turkey slaughter and further processing establishments, including establishments that produce comminuted poultry. Through this checklist survey, FSIS will document whether establishments made changes to their HACCP plans in response to the required reassessment or whether changes were made before the mandatory reassessment, and will capture a general description of the type of changes made. IPP will be instructed to share establishment responses to the checklist with establishment management in order to best ensure that the information is complete. Establishments that disagree with the IPP checklist entries will be encouraged to provide supporting rationale for why the responses should be changed.

The completed survey will enable the Agency to identify which establishments have reassessed HACCP plans for NRTE comminuted poultry products, based on the outbreak information discussed above.

FSIS will subsequently evaluate establishments that produce NRTE comminuted poultry products to collect in-depth information on changes made. FSIS will evaluate information gathered in the survey and may conduct FSAs of establishments producing NRTE comminuted poultry products. The Agency will decide on the conditions under which it will conduct any other evaluations for establishments producing NRTE comminuted poultry products. Consistent with current Agency practices, FSIS may conduct a "for cause" FSA in response to production and shipment of adulterated product. In response to the survey results discussed above, FSIS may consider conducting a "for cause" FSA, if FSIS has any concerns regarding that establishment's food safety system.

Once FSIS has evaluated such establishments, it intends to publish guidance for industry on best practices to reduce Salmonella in comminuted poultry. In addition, the Agency expects to use the results in designing targeted verification activities.

FSIS recommends that manufacturers of comminuted products derived from cattle, hogs, and sheep or comminuted poultry

products derived from poultry other than chicken or turkeys also take note of the factors contributing to the recent comminuted turkey product outbreaks. These manufacturers should consider the instructions in this notice with regard to assessing whether their food safety systems present similar vulnerabilities.

#### Adulteration of Product Associated with Outbreaks

When NRTE poultry or meat products are associated with an illness outbreak and contain pathogens that are not considered adulterants, FSIS likely will consider the product linked to the illness outbreak to be adulterated under 21 U.S.C. 453 (g) (3) or 21 U.S.C. 601(m) (3) because the product is "... unsound, unhealthful, unwholesome, or otherwise unfit for human food." In such cases, the Agency would request that the establishment recall the product if it is still in commerce.

FSIS will also evaluate whether the particular product associated with the illness outbreak may also be adulterated because it was "... prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (21 U.S.C. 453(g) (4) or 21 U.S.C. 601(m) (4)). FSIS would likely find that such product is adulterated because it was produced under insanitary conditions where the establishment produced the product of concern under conditions that did not adequately

address control of the pathogen in the product associated with the illness.

The Agency would also likely determine the insanitary conditions to be continuing in the establishment until the establishment demonstrates that it has regained control of its production processes and re-established sanitary conditions under which the product is produced so that the establishment is able to produce unadulterated product.

FSIS would also have to evaluate whether the type of product produced at other establishments, when demonstrably linked to product associated with the outbreak, is adulterated because it was produced under substantially similar processes and insanitary conditions. For example, associated product at another establishment produced from birds that came from the same grow-out house as the birds that were the source of the product associated with the illness outbreak, and that were subject to substantially similar processing conditions, may also be determined to be adulterated by the Agency.

FSIS would not be likely, however, to consider product of the same type adulterated though it is found to have the pathogen associated with the illness outbreak, provided it was produced in other establishments that have no relationship to product involved in the illness outbreak. A determination of adulteration would be specific to the product linked to the

illness outbreak and to the conditions in the establishment where that product was produced.

#### Agency Verification Sampling and Testing

The Agency is expanding its Salmonella Verification Sampling Program to include all non-breaded, non-battered "NRTE comminuted" chicken or turkey products in addition to the currently sampled NRTE ground chicken and turkey. In a way similar to the process of grinding product, the process of producing comminuted product, whether mechanically deboned or mechanically separated, leads to the distribution of pathogens throughout the product. These techniques differ mainly in the equipment used and the source materials (i.e., boneless meat versus meat with bone attached). Both mechanically deboned product and mechanically separated product were used in the product associated with one of the outbreaks discussed in this notice. The product involved in the outbreak was likely not subject to FSIS sampling. In the past, mechanically separated product was not typically used in poultry product sold to consumers in an NRTE product. At this time, however, mechanically separated product may be included in such product, especially for export. For all these reasons, FSIS will begin sampling non-breaded, non-battered comminuted product for Salmonella. In addition, FSIS expects to use the verification testing program as the mechanism to obtain samples to determine

the prevalence of Salmonella in comminuted poultry and will use the results from this sampling to develop performance standards for these products. FSIS also expects to analyze the samples for Campylobacter, as well as for other microorganisms that could serve as indicators of inadequate process control.

As explained above, "NRTE comminuted poultry" products to be sampled include any non-breaded, non-battered raw or otherwise NRTE product that has been ground, mechanically separated, or hand- or mechanically-deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. The Agency will also include in its sampling non-breaded, non-battered NRTE comminuted poultry product after other ingredients such as spices have been added, since the Agency expects establishments to control pathogens in final product regardless of the source of the pathogens. Consistent with FSIS's current Salmonella sampling procedures for NRTE product, when the establishment either processes all comminuted product into RTE product or moves all such product to another official federally-inspected domestic establishment for further processing into RTE product, such product will not be subject to Agency sampling. The Agency will collect comminuted NRTE samples in establishments with an average daily production of greater than 1,000 pounds over the past month, but this may change as the program progresses.

A sampling change will be initiated to allow for a more accurate measurement of the incidence of Salmonella. Beginning 90 days after publication of this notice, the sampling for these comminuted poultry products will begin with a new larger standard size for its verification samples as the Agency completes validation studies on moving its microbiological testing from a 25 gram sample size to 325 grams. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for two pathogens.

Meanwhile, based on analysis of data from three consecutive years, Fiscal Year (FY) 2009 to FY2011, FSIS is considering reducing the number of samples in a set from 53 to 26 samples. FY2009 - 2011 data analysis showed that reducing samples from 53 to 26 will not compromise the ability to detect non-compliant establishments. With this change, based on current standards, FSIS is considering accepting a maximum of 15 positive samples in a 26-sample ground turkey set to meet the performance standard and a maximum of seven positive samples for such a set to count toward Category 1 status. For ground chicken, based on current standards, FSIS is considering accepting a maximum of 13 positive samples in a 26-sample set to meet the performance standard and a maximum of six positive samples for such a set to count toward Category 1 status. Because a reduction in sample set size could increase the



number of sets that can be performed in a given period of time, the possibility exists that this modification may result in a greater number of non-compliant establishments detected in that time period, providing a better reflection of current production practices and increasing the efficiency of FSIS resource utilization.

The original Salmonella performance standards were established based on industry averages (percent positive samples) estimated from baseline surveys conducted more than a decade ago. The current standards were designed such that establishments with sampling results above an average (or expected) result would be considered non-compliant with the standard. Recently, FSIS has explored designing performance standards to achieve a public health objective. For example, the Healthy People 2020 goal for human salmonellosis is a 25 percent reduction. FSIS intends to apply its Category 1 ranking for ground chicken and turkey product to comminuted product to mark the level of performance at which all establishments producing such products should maintain process control. The Agency's Category 1 approach for the current performance standard includes establishments with sample results at 50 percent or less of the relevant performance standard, as detailed in a February 2006 Federal Register notice

(<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://w>

[www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-026N.htm](http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-026N.htm);

<http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2010-0029.htm>). For ground chicken the performance standard is 44.6 percent and the acceptable number of positive samples per set is 26 of 53. For ground turkey the performance standard is 49.9 percent and the acceptable number of positive samples per set is 29 of 53.

FSIS intends to conduct a risk assessment based on at least three months of these new sampling and testing results and issue a new performance standard for these products for Salmonella and likely Campylobacter as well. With publication of this notice, FSIS will discontinue sampling sets for ground poultry product, except for establishments in category 3. When FSIS stops testing sets at establishments, FSIS recommends that they assess whether they meet the category 1 standard. Establishments in category 3 are those that have not been able to maintain consistent process control over the previous two Salmonella verification testing sets and have shown highly variable process control over the most recent set (i.e., the most recent set does not meet the performance standard and any result in prior set). For these establishments, FSIS will continue to schedule sets for ground chicken or turkey and would also sample other comminuted chicken or turkey products. The Agency requests comment on whether, given the relatively

high prevalence of Salmonella in comminuted chicken and turkey product, it should apply to these product classes a more stringent measure of 25 percent of the national prevalence for defining Category 1 rather than the traditional measure of 50 percent of the national prevalence for defining Category 1. That is, the traditional 50 percent reduction applied to the current standard of 44.6 for ground chicken and 49.9 percent for ground turkey would give a Category 1 standard of approximately 22 and 24 percent, respectively. Applying a more stringent measure of 25 percent of the national prevalence to these product classes would give a Category 1 standard of approximately 11 and 12 percent, respectively. FSIS believes that establishments would seek to improve process control so as to remain compliant with a revised performance standard and that, as a result, a substantial number of illnesses would be averted. In addition, a reduction of Category 1 to 25 percent of the performance standard would be consistent with the goals of the Healthy People 2020 initiative.

Except for category 3 establishments, FSIS will discontinue the concept of set testing for ground and comminuted chicken or turkey at least until it establishes new performance standards for these products. For samples that are not collected as part of sets, FSIS field service laboratories will perform qualitative testing for the presence or absence of

Salmonella using the same methodology, discard criteria, and reporting as those currently in place. Samples that screen positive will be analyzed, i.e., the Salmonella organisms present will be enumerated, using the MPN (Most Probable Number) procedure.

#### Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this notice in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements for this notice, which informs establishments that produce not ready-to-eat comminuted poultry products that they need to reassess their HACCP Plans, have already been accounted for in the Pathogen Reduction/HACCP Systems information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Pathogen Reduction/HACCP Systems information collection is 0583-0103.

#### USDA Nondiscrimination Statement

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#### Additional Public Notification

FSIS will announce this document online through the FSIS Web page located at [http://www.fsis.usda.gov/regulations\\_&\\_policies/Federal\\_Register\\_Notices/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Federal_Register_Notices/index.asp).

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for

industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/News & Events/Email Subscription/>. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC, on November 30, 2012.

Alfred V. Almanza,

Administrator, FSIS.

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